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Elaine C. Stracker

## PATENT

Attorney's Docket No.: 00041.10CON

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.

Serial No.: 10/735,496

Filed: 12/12/2003

Title DELIVERY OF COMPOUNDS FOR THE TREATMENT OF  
MIGRAINE THROUGH AN INHALATION ROUTE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their continuing duty of disclosure under 37 CFR §§ §1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

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Respectfully submitted,

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Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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# TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number 10/735,496

Filing Date 12/12/2003

First Named Inventor Joshua D. Rabinowitz

Art Unit Not yet known

Examiner Name To be assigned

Attorney Docket Number 00041.10CON

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
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Form PTO-1449  
U.S. PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: 00041.10 CON

Application Number: 10/735,496

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/12/2003

Group Art Unit: Not Yet Known

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	02/02/1971	3,560,607	Hartley et al.			
	2.	05/27/1980	Re. 30,285	Babington			
	3.	01/23/1990	4,895,719	Radhakrishnun et al.			
	4.	09/17/1991	5,049,389	Radhakrishnun			
	5.	02/14/1995	5,388,574	Ingebrethsen			
	6.	08/13/1996	5,544,646	Lloyd et al.			
	7.	12/09/1997	5,694,919	Rubsamen et al.			
	8.	04/07/1998	5,735,263	Rubsamen et al.			
	9.	04/14/1998	5,738,865	Baichwal et al.			
	10.	06/02/1998	5,758,637	Ivri et al.			
	11.	06/16/1998	5,767,117	Moskowitz			
	12.	06/29/1999	5,915,378	Lloyd et al.			
	13.	08/10/1999	5,934,272	Lloyd et al.			
	14.	09/28/1999	5,957,124	Lloyd et al.			
	15.	10/05/1999	5,960,792	Lloyd et al.			
	16.	11/30/1999	5,993,805	Sutton et al.			
	17.	03/28/2000	6,041,777	Faithfull et al.			
	18.	04/18/2000	6,051,566	Bianco			
	19.	08/01/2000	6,095,153	Kessler et al.			
	20.	08/15/2000	6,102,036	Slutsky et al.			
	21.	06/05/2001	6,241,969	Saidi et al.			
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	23.	10/23/2001	6,306,431	Zhang et al.			
	24.	04/23/2002	6,376,550	Raber et al.			
	25.	10/08/2002	6,461,591	Keller et al.			

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	26.	01/14/2003	6,506,762	Horvath et al.			
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	33.	08/22/2002	US 2002/0112723	Schuster et al.			
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	37.	08/04/2003	10/633,876	Hale et al.			
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	39.	12/30/2003	10/749,537	Rabinowitz et al.			
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	52.	01/30/2004	10/769,046	Rabinowitz et al.			

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53.	01/30/2004	10/769,051	Rabinowitz et al.
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109.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
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	111.	08/12/2004	US 2004/0156788	Rabinowitz et al.				
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	114.	08/12/2004	US 2004/0156791	Rabinowitz et al.				

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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES      NO
	115.	03/14/1990	EP 0 358 114	Europe			
	116.	07/03/2001	EP 1 080 720	Europe			
	117.	08/29/2001	EP 0 606 486	Europe			
	118.	04/11/1996	WO 96/09846	WIPO			
	119.	05/09/1996	WO 96/13161	WIPO			
	120.	05/09/1996	WO 96/13290	WIPO			
	121.	05/09/1996	WO 96/13291	WIPO			
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	123.	10/03/1996	WO 96/30068	WIPO			
	124.	08/07/1997	WO 97/27804	WIPO			
	125.	05/28/1998	WO 98/22170	WIPO			
	126.	07/23/1998	WO 98/31346	WIPO			
	127.	08/27/1998	WO 98/36651	WIPO			
	128.	04/08/1999	WO 99/16419	WIPO			
	129.	12/16/1999	WO 99/64094	WIPO			
	130.	01/06/2000	WO 00/00176	WIPO			
	131.	01/06/2000	WO 00/00215	WIPO			
	132.	05/18/2000	WO 00/27363	WIPO			

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133.	05/25/2000	WO 00/29053	WIPO			
134.	09/17/2000	WO 00/47203	WIPO			
135.	11/02/2000	WO 00/64940	WIPO			
136.	11/09/2000	WO 00/66084	WIPO			
137.	11/09/2000	WO 00/66206	WIPO			
138.	12/21/2000	WO 00/76673	WIPO			
139.	01/25/2001	WO 01/05459	WIPO			
140.	03/28/2002	WO 02/24158	WIPO			

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*(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
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	142.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology</i> (Berl). 102:443-450.
	143.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
	144.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society</i> . 966-974.
	145.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology</i> . 32(5):591-600.
	146.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology</i> . 93(3): 619-628.
	147.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.
	148.	Gonda,I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

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149.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i> . 36(1):1-7.
150.	Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 µm," <i>J. Aerosol Sci.</i> 17(5):811-822.
151.	Huizer, H., "Analytical studies on illicit heron. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.
152.	Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.
153.	Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics</i> . 279(1):69-76.
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156.	Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i> , (1997) 173:201-224.
157.	Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i> . 53:111-120.
158.	Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE"
159.	Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.
160.	Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.
161.	Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.
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163.	Vapotronics, Inc. (1998) located at <a href="http://www.vapotronics.com.au/banner.htm">http://www.vapotronics.com.au/banner.htm</a> , 11 pages, (visited on June 5, 2000).
164.	Ward, M.E. MD, et al. (December 1997). "Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System," <i>Clinical Pharmacology &amp; Therapeutics</i> 62(6):596-609.

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165. Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i> . 55(2):237-248.			
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	8.	04/07/1998	5,735,263	Rubsamen et al.			
	9.	04/14/1998	5,738,865	Baichwal et al.			
	10.	06/02/1998	5,758,637	Ivri et al.			
	11.	06/16/1998	5,767,117	Moskowitz			
	12.	06/29/1999	5,915,378	Lloyd et al.			
	13.	08/10/1999	5,934,272	Lloyd et al.			
	14.	09/28/1999	5,957,124	Lloyd et al.			
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	18.	04/18/2000	6,051,566	Bianco			
	19.	08/01/2000	6,095,153	Kessler et al.			
	20.	08/15/2000	6,102,036	Slutsky et al.			
	21.	06/05/2001	6,241,969	Saidi et al.			
	22.	07/03/2001	6,255,334	Sands			
	23.	10/23/2001	6,306,431	Zhang et al.			
	24.	04/23/2002	6,376,550	Raber et al.			
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63.	03/03/2004	10/792,239	Hale et al.			
64.	03/31/2004	10/813,721	Rabinowitz et al.			
65.	03/31/2004	10/813,722	Rabinowitz et al.			
66.	03/31/2004	10/814,690	Rabinowitz et al.			
67.	03/31/2004	10/814,998	Rabinowitz et al.			
68.	04/01/2004	10/815,527	Rabinowitz et al.			
69.	04/01/2004	10/816,407	Rabinowitz et al.			
70.	04/01/2004	10/816,492	Rabinowitz et al.			
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72.	08/04/2004	10/912,462	Hale et al.			
73.	01/23/2003	US 2003/0015196	Hodges et al.			
74.	04/03/2003	US 2003/0062042	Wensley et al.			
75.	11/13/2003	US 2003/0209240	Hale et al.			
76.	01/02/2003	US 2003/0000518	Rabinowitz et al.			
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78.	01/09/2003	US 2003/0005925	Hale et al.			
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80.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
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82.	01/16/2003	US 2003/0012738	Rabinowitz et al.			
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84.	01/23/2003	US 2003/0015189	Rabinowitz et al.			
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87.	01/23/2003	US 2003/0017115	Rabinowitz et al.			
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89.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
90.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
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92.	01/23/2003	US 2003/0017120	Rabinowitz et al.			
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98.	05/27/2004	US 2004/010148	Hale et al.			
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100.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
101.	01/15/2004	US 2004/0009128	Rabinowitz et al.			
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104.	06/03/2004	US 2004/0105818	Hale et al.			
105.	06/03/2004	US 2004/0105819	Hale et al.			
106.	07/01/2004	US 2004/0126326	Rabinowitz et al.			
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	111.	08/12/2004	US 2004/0156788	Rabinowitz et al.				
	112.	08/12/2004	US 2004/0156789	Rabinowitz et al.				
	113.	8/12/2004	US 2004/0156790	Rabinowitz et al.				
	114.	08/12/2004	US 2004/0156791	Rabinowitz et al.				

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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	115.	03/14/1990	EP 0 358 114	Europe			
	116.	07/03/2001	EP 1 080 720	Europe			
	117.	08/29/2001	EP 0 606 486	Europe			
	118.	04/11/1996	WO 96/09846	WIPO			
	119.	05/09/1996	WO 96/13161	WIPO			
	120.	05/09/1996	WO 96/13290	WIPO			
	121.	05/09/1996	WO 96/13291	WIPO			
	122.	05/09/1996	WO 96/13292	WIPO			
	123.	10/03/1996	WO 96/30068	WIPO			
	124.	08/07/1997	WO 97/27804	WIPO			
	125.	05/28/1998	WO 98/22170	WIPO			
	126.	07/23/1998	WO 98/31346	WIPO			
	127.	08/27/1998	WO 98/36651	WIPO			
	128.	04/08/1999	WO 99/16419	WIPO			
	129.	12/16/1999	WO 99/64094	WIPO			
	130.	01/06/2000	WO 00/00176	WIPO			
	131.	01/06/2000	WO 00/00215	WIPO			
	132.	05/18/2000	WO 00/27363	WIPO			

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	133.	05/25/2000	WO 00/29053	WIPO			
	134.	09/17/2000	WO 00/47203	WIPO			
	135.	11/02/2000	WO 00/64940	WIPO			
	136.	11/09/2000	WO 00/66084	WIPO			
	137.	11/09/2000	WO 00/66206	WIPO			
	138.	12/21/2000	WO 00/76673	WIPO			
	139.	01/25/2001	WO 01/05459	WIPO			
	140.	03/28/2002	WO 02/24158	WIPO			

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	141.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	142.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology (Berl).</i> 102:443-450.
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149.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i> . 36(1):1-7.
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159.	Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.
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165.	Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i> . 55(2):237-248.		

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PTO/SB/08 (2-92)	Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SEP 24 2004

PTO/SB/08 (2-92)

Sheet 1 of 8

<p style="text-align: center;"><b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b></p> <p><i>(Use several sheets if necessary)</i></p>	Docket Number: 00041.10 CON		Application Number: 10/735,496
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	1.	02/02/1971	3,560,607	Hartley et al.			
	2.	05/27/1980	Re. 30,285	Babington			
	3.	01/23/1990	4,895,719	Radhakrishnun et al.			
	4.	09/17/1991	5,049,389	Radhakrishnun			
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	66.	03/31/2004	10/814,690	Rabinowitz et al.			
	67.	03/31/2004	10/814,998	Rabinowitz et al.			
	68.	04/01/2004	10/815,527	Rabinowitz et al.			
	69.	04/01/2004	10/816,407	Rabinowitz et al.			
	70.	04/01/2004	10/816,492	Rabinowitz et al.			
	71.	04/01/2004	10/816,567	Rabinowitz et al.			
	72.	08/04/2004	10/912,462	Hale et al.			
	73.	01/23/2003	US 2003/0015196	Hodges et al.			
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	75.	11/13/2003	US 2003/0209240	Hale et al.			
	76.	01/02/2003	US 2003/0000518	Rabinowitz et al.			
	77.	01/09/2003	US 2003/0005924	Rabinowitz et al.			
	78.	01/09/2003	US 2003/0005925	Hale et al.			
	79.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
	80.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
	81.	01/16/2003	US 2003/0012737	Rabinowitz et al.			

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Form PTO-1449				Docket Number: 00041.10 CON	Application Number: 10/735,496
				Applicant: Joshua D. RABINOWITZ et al.	
				Filing Date: 12/12/2003	Group Art Unit: Not Yet Known

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88.	01/23/2003	US 2003/0017116	Rabinowitz et al.			
89.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
90.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
91.	01/23/2003	US 2003/0017119	Rabinowitz et al.			
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93.	1/30/2003	US 2003/0021753	Rabinowitz et al.			
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97.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
98.	05/27/2004	US 2004/010148	Hale et al.			
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100.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
101.	01/15/2004	US 2004/0009128	Rabinowitz et al.			
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105.	06/03/2004	US 2004/0105819	Hale et al.			
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110.	07/01/2004	US 2004/0127490	Rabinowitz et al.			

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	114.	08/12/2004	US 2004/0156791	Rabinowitz et al.			

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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	115.	03/14/1990	EP 0 358 114	Europe			
	116.	07/03/2001	EP 1 080 720	Europe			
	117.	08/29/2001	EP 0 606 486	Europe			
	118.	04/11/1996	WO 96/09846	WIPO			
	119.	05/09/1996	WO 96/13161	WIPO			
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	121.	05/09/1996	WO 96/13291	WIPO			
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	127.	08/27/1998	WO 98/36651	WIPO			
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	131.	01/06/2000	WO 00/00215	WIPO			
	132.	05/18/2000	WO 00/27363	WIPO			

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	133.	05/25/2000	WO 00/29053	WIPO			
	134.	09/17/2000	WO 00/47203	WIPO			
	135.	11/02/2000	WO 00/64940	WIPO			
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<p>149. Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i>. 36(1):1-7.</p> <p>150. Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 <math>\mu\text{m}</math>," <i>J. Aerosol Sci.</i> 17(5):811-822.</p> <p>151. Huizer, H., "Analytical studies on illicit heroin. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.</p> <p>152. Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.</p> <p>153. Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics</i>. 279(1):69-76.</p> <p>154. Martin, B.R. and Lue, L.P. (May/June 1989). "Pyrolysis and Volatilization of Cocaine," <i>Journal of Analytical Toxicology</i> 13:158-162.</p> <p>155. Mattox, A.J. and Carroll, M.E., (1996). "Smoked heroin self-administration in rhesus monkeys," <i>Psychopharmacology</i>, 125:195-201.</p> <p>156. Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i>, (1997) 173:201-224.</p> <p>157. Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i>. 53:111-120.</p> <p>158. Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE"</p> <p>159. Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.</p> <p>160. Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.</p> <p>161. Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.</p> <p>162. Sekine, H. and Nakahara, Y. (1987). "Abuse of Smoking Methamphetamine Mixed with Tobacco: 1. Inhalation Efficiency and Pyrolysis Products of Methamphetamine," <i>Journal of Forensic Science</i> 32(5):1271-1280.</p> <p>163. Vapotronics, Inc. (1998) located at <a href="http://www.vapotronics.com.au/banner.htm">http://www.vapotronics.com.au/banner.htm</a>, 11 pages, (visited on June 5, 2000).</p> <p>164. Ward, M.E. MD, et al. (December 1997). "Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System," <i>Clinical Pharmacology &amp; Therapeutics</i> 62(6):596-609.</p>			
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165.	Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i> . 55(2):237-248.		

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